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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,805	12/02/2003	Harold H. Schmitz	1010-133US1	3329
32260	7590	03/26/2007	EXAMINER	
NADA JAIN, P.C. 560 White Plains Road, Suite 460 Tarrytown, NY 10591			LEITH, PATRICIA A	
ART UNIT		PAPER NUMBER		
1655				
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	03/26/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/725,805	SCHMITZ, HAROLD H.
	Examiner	Art Unit
	Patricia Leith	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 February 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 34-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 34-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/07 has been entered.

Claims 34-53 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection remains standing for the reasons of record. These claims are rejected for the same reasoning as set forth in the previous Office action pertaining to claims 5-8 and 13-18 and 33.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues first that 1) levels of TGF- β differ in individual subjects with high variability, (2) when samples from individual are incubated with a series of flavanols and procyanidins, the % change of TGF- β varies from "positive to negative even for the same compound and (3) "Applicants discovered that this differential response was due to the differences in the starting (i.e., baseline) levels of TGF- β , i.e., the levels prior to exposure to the tested compounds. When the tested individuals were categorized on the basis of their starting TGF- β levels, a clear trend was observed in the way in which the tested compounds modulated TGF- β levels" (pp. 4-5 Remarks).

Applicant further argues that Table 3 demonstrates:

"individuals categorized as low baseline producers responded to monomer with an increase in their TGF- β levels; in contrast, the same compound when administered to high baseline

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producers, caused a decrease in TGF- β levels. The same pattern is observed for all other tested compounds...In other words, it is the starting level of TGF- β which determines how an individual will respond to a given flavanol or procyandin. Therefore, if a subject responds to a monomer by increasing its TGF- β , it is classified as a low baseline producer; conversely, if a subject responds to monomer by decreasing its TGF- β , it is classified as a high baseline producer"

The Examiner agrees with (1) and (2) above, as Applicant is indicating what is found in the Instant specification. However, Applicant indicates in (3), as well as in the Instant claims, that it is the measurement of TGF- β values which base the outcome of 'low' and 'high' baseline levels. It is not found in the Instant specification where Applicant has determined 'low' and 'high' baseline levels *based upon the change in TGF- β due to administration of flavanols*. It is clear from the Instant specification that these identifiers were given to individuals based upon their TGF- β levels *prior to the proanthocyanidin administration (in-vitro)*. Therefore, it is deemed that Applicant was not in possession of the method as Instantly claimed.

It is not found convincing that Applicant has invented a method for determining low or high baseline levels, in that again, the blood samples were taken from healthy individuals and also that the statistics for individuals appears to be insignificant (e.g., Fig. 1). Further, it is not known if Applicant disregarded any outliers present in the data, and it appears that most of the data points are concentrated within the -50% to +50% range, with a significant portion below the 0% range. Also, it is not known what the statistics for each individual sample was; that is, only averages are given in Figures

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2 and 4. Therefore, it is not known if the data found in Figures 2 and 3 are truly significant, because it is not known, for example, how many samples in the 'High Baseline' tested higher than the average, and how many samples in the 'Low Baseline' tested lower than the average. It appears that if the median rather than the mean is taken from the data found in Figure 1, that the data is not significant, as the most concentrated portions can again, be found within the -50% to +50% range. Also, it is not clear, and Applicant may wish to clarify this point; how the media was handled. It is assumed that the media only contained one sample of each individual's PBMC's absent any exogenous phytochemicals, was treated under the same conditions as the samples, and it was these individual sample controls which were compared with the same individual's PBMC's with the phytochemicals added to the medium.

Claims 34-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is deemed that the claims as instantly recited do not satisfy the enablement requirement under this statute because one of skill in the art could not use the invention for its intended purpose.

Applicant's have not set forth adequate information which would enable the skilled worker to repeat the processes set forth in the Instant claims. It is not clear in the Instant specification whether the process is repeatable in individuals because the data found in Figure 1 appears to be insignificant, and the data found in Figures 2 and 3 are means compiled from a small sample study of 13 individuals. Therefore, it is unclear if a change in TGF- β calculated in response to procyanidin administration (*in-vivo* or *in-vitro*) would necessarily indicate that the individual is a 'low' or 'high' baseline producer because data is not clearly presented for each individual. For example, if an individual with an active cancer was tested for TGF- β levels, and their sample was compared with PBMC's cultured with polyphenols, would a positive change in the TGF- β concentration value indicate that the individual is a 'low baseline' TGF- β producer? This is not understood because it is accepted that persons with cancer or an immunological disturbance would more than likely have higher or lower than *their* 'normal' concentration of TGF- β . Therefore, it does not appear that the method could be consistent and reproducible for the majority of individuals.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

March 14, 2007

